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No. 90-740

In the Supreme Court of the United States

OCTOBER TERM, 1990

DAKOTA CHEESE, INC., AND JAMES DEE, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the district court erred in deciding as a matter of law that Food and Drug Administration regulations prohibit the addition of calcium caseinate to mozzarella cheese sold under contract to the federal government.

2. Whether it was error for the district court to rule that the meaning of the pertinent FDA regulations was a question of law, after the court initially stated that it would treat the issue as a question of fact for the jury.

3. Whether the pertinent FDA regulations are so vague as to render the criminal prosecution based on petitioners' failure to comply with them a violation of the Due Process Clause.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. A1-A12) is reported at 906 F.2d 335.

JURISDICTION

The judgment of the court of appeals was entered on June 13, 1990. A petition for rehearing was denied on August 9, 1990. Pet. App. A13. The petition for a writ of certiorari was filed on November 6, 1990. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

After a jury trial in the United States District Court for the District of South Dakota, petitioners were each convicted on one count of conspiring to defraud the United States, in violation of 18 U.S.C. 371, and four counts of making false statements to the Commodity Credit Corporation, in violation of 15 U.S.C. 714m(a).[1] Petitioner Dakota Cheese, Inc., was placed on unsupervised probation for one year and fined $200,000. Petitioner Dee was fined $200,000. The court of appeals affirmed.[2]

1. The Commodity Credit Corporation of the Department of Agriculture (CCC) from time to time purchases cheese for use in the National School Lunch Program or other domestic donation programs. During 1984 and 1985, petitioners—Dakota Cheese, Inc., and its president, James Dee—entered into four contracts to sell mozzarella cheese to the CCC. Pet. 4; Pet. App. A4. The specifications in the contract provided that

> [t]he cheese shipped to CCC shall be low moisture part-skim mozzarella cheese as defined by Food and Drug Administration, U.S. Department of Health, Education and Welfare in its Definitions and Standards under the Federal Food, Drug and Cosmetics Act, as amended, in effect at time of shipping.

Pet. 7. The pertinent FDA definition and standard of identity regulation provides that "[l]ow moisture

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[1] Petitioner Dakota Cheese, Inc., was also convicted on four counts of making false claims, in violation of 18 U.S.C. 287, and nine counts of mail fraud, in violation of 18 U.S.C. 1341.

[2] The two paragraphs describing the convictions and sentences are missing from the court of appeals' opinion as printed at Pet. App. A2, but can be found at 906 F.2d at 336.

mozzarella cheese is the food prepared from milk and other ingredients specified in this section." 21 C.F.R. 133.156(a). Moreover, the FDA regulation on food standards in general provides that a food does not conform to the definition and standard of identity "[i]f it contains an ingredient for which no provision is made in such definition and standard." 21 C.F.R. 130.8(a).

The evidence at trial showed that in 1983, Dakota Cheese first started using calcium caseinate in making the low moisture, part skim mozzarella cheese that it sold to the federal government. Pet. App. A4. Calcium caseinate, containing a foster protein that is one of the chief ingredients of milk, is ordinarily used in breakfast bars, protein supplements, cheese substitutes, and imitation cheese. *Id.* at A2 n.2, A3. Calcium caseinate is not one of the ingredients specified in 21 C.F.R. 133.156 as allowable for use in mozzarella cheese. See Pet. App. A17-A20.[3] Dakota Cheese's use of calcium caseinate resulted in greater yields of cheese products. See *id.* at A4. Accordingly, from September 1984 through August 1985, on CCC contracts worth more than $6 million, petitioners managed to save $695,000 by providing cheese that did not meet the specifications in the contracts. *Id.* at A6.

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[3] The other ingredients specified in the regulation are cream, skim milk, concentrated skim milk, nonfat dry milk, and water. 21 C.F.R. 133.156(c)(1). In the cheesemaking process, the use of lactic acid-producing bacteria, vinegar, rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme, purified calcium chloride, and safe and suitable artificial coloring are allowed. 21 C.F.R. 133.156(b). The regulation also permits safe and suitable antimycotic agents to be added. 21 C.F.R. 133.156(d).

Petitioners' scheme—essentially amounting to substituting imitation cheese for the real cheese required by the CCC contracts—began to unravel as a result of conversations overheard in the company break room by George Sinkie, an employee of Dakota Cheese. Sinkie questioned the legality of the use of calcium caseinate and later telephoned the South Dakota Department of Agriculture. The Department's director of dairy and egg inspection told Sinkie, based on his reading of the pertinent federal regulations, that the use of calcium caseinate was illegal unless the cheese was labeled as imitation cheese. Pet. App. A4. Sinkie then informed the Dakota Cheese plant foreman that he would no longer fortify the cheese with calcium caseinate, because the company was not identifying its product as imitation cheese. The plant foreman told Sinkie that if he would not do so, he should take three days off without pay. Sinkie chose to quit. *Ibid.*

Petitioner Dee told his employees that the use of calcium caseinate was a trade secret. Dee also admitted to them that he could be in trouble if government officials learned of its use. Dee therefore directed employees to remove the outer identifying wrappers from the calcium caseinate bags before moving them from the warehouse to the cheese plant, when state or federal inspectors were present. In the case of bags that were already at the plant, Dee told the employees to return them to the warehouse if inspectors were expected. Dee also directed that truck loads of calcium caseinate be removed from the warehouse before inspectors arrived. Pet. App. A5. One time, Dee drove around town looking for the inspector's car while the caseinate was being loaded on a truck for removal from the warehouse. He told one employee, "I don't want to get caught with this shit." *Ibid.* Dee also told another employee that he did not

want the government to know about the use of the caseinate, and that he did not want the caseinate bags "around for evidence." *Ibid.* He once told his employees to "get rid of [the calcium caseinate] as soon as you can. If the USDA inspectors come in the plant today, they could fine * * * the hell out of me, if they seen [sic] it." *Id.* at A6.[4]

2. The court of appeals affirmed. Pet. App. A1-A12. In the court of appeals, petitioners first contended that the district court had directed a verdict on a critical issue of fact—whether the FDA regulations permit the use of calcium caseinate. The court rejected that claim, holding that the district court had properly decided that issue as one of law. As the court of appeals pointed out, see *id.* at A9-A10, the district court required the jury to decide as a matter of fact whether petitioners used calcium caseinate and whether they knew federal law prohibited its use. The district court took from the jury only the legal issue of whether the FDA regulations permitted the use of calcium caseinate.

Petitioners next argued that the district court's determination that the meaning of the pertinent FDA regulations was a question of law, after initially stating that it intended to leave that to the jury, amounted to prejudicial error. The court of appeals "acknowledge[d] the force of [petitioners'] argument," but pointed out that "much of the evidence submitted by [petitioners] bore on the reasonableness of their belief—and thus their lack of knowledge to

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[4] In September 1985, an auditor from the Milk Market Administrator's office of the USDA audited Dakota Cheese. In anticipation of the audit, the company had altered copies of its purchase invoices by removing the words "calcium caseinate." Pet. App. A6.

the contrary—that such use was permitted." Pet. App. A10. The court of appeals noted that the district court should have made its ruling regarding the legal nature of the construction of the regulations earlier in the trial, but the court added that it was "not convinced that [the district court's] failure to do so resulted in such fundamental unfairness to [petitioners] that their convictions must be reversed." *Ibid.*

The court of appeals rejected petitioners' argument that the FDA regulations could be read to permit the use of calcium caseinate. As the court pointed out, the regulations permit the use of milk and other "specified" ingredients, but those "other ingredients listed do not include calcium caseinate." Pet. App. A11. The court accordingly concluded that "the language of the regulations is clear and * * * the contract specifications did not permit the use of calcium caseinate." *Ibid.*

ARGUMENT

1. Petitioners contend (Pet. 12-17) that the district court erred in deciding as a matter of law that FDA regulations prohibit the addition of calcium caseinate to mozzarella cheese sold under contract to the federal government.

After reviewing the pertinent regulations, the district court determined that calcium caseinate is not a permitted ingredient of mozzarella cheese, and the court so instructed the jury. As the court of appeals observed, Pet. App. A10, the district court did not direct the jury to find that petitioners had added caseinate to their cheese, or that they knew it was unlawful. The court instructed the jury only as to what the regulations provided, namely, that calcium

caseinate is not a permitted additive to mozzarella cheese sold to the federal government.[5]

2. Petitioners next contend (Pet. 17-20) that they were deprived of a fair trial when the district court, after admitting evidence on the meaning of the regulations, removed that issue from the jury's consideration. The principal issue contested at trial was petitioners' intent, namely, whether they knowingly violated the regulations and defrauded the government. As a result, evidence on the meaning of the regulations was relevant and could not have harmed petitioners. If anything, allowing jurors to hear evidence that the regulations, in the view of certain witnesses, did not prohibit the use of calcium caseinate could only have helped petitioners in their attempt to cast doubt in the jurors' minds as to whether petitioners knowingly violated the regulations. Moreover, the error could not have affected petitioners' trial strategy, since they planned all along to show —and tried to show at trial—that any violation on their part was not intentional.

Petitioners also claim (Pet. 20) that the law-of-the-case doctrine precluded the district court from

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[5] Petitioners assert (Pet. 13-16) that the court of appeals' decision conflicts with *United States* v. *White Horse*, 807 F.2d 1426 (8th Cir. 1986), and *United States* v. *Johnson*, 718 F.2d 1317 (5th Cir. 1983) (en banc). In those cases, the district courts had erroneously decided the question whether certain evidence satisfied a statutory element of the offense. Here, by contrast, the district court merely construed the pertinent FDA regulations and left it to the jury to decide whether petitioners had complied with those regulations. In any event, with respect to the alleged conflict between the decision in this case and the decision in *White Horse*, any such conflict would be an intracircuit conflict, which does not present an issue requiring this Court's review. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

correcting its initial erroneous ruling that the issue was one of fact. That claim is meritless. A prior ruling may be reconsidered as long as a judgment has not been entered. *Christianson* v. *Colt Indus. Operating Corp*, 486 U.S. 800, 815-818 (1988); *Washington* v. *Washington State Fishing Vessel Ass'n*, 443 U.S. 658, 672 n.19 (1979). A court has the "power to revisit prior decisions of its own * * * in any circumstance." *Christianson*, 486 U.S. at 817. Although "as a rule, courts should be loathe to do so in the absence of extraordinary circumstances," such as where the initial decision was clearly erroneous and would work a manifest injustice, *ibid.*,[6] here it clearly would have been improper to allow the jury to decide an issue of law.

3. Finally, petitioners contend (Pet. 21-27) that the pertinent FDA regulations are so vague as to render the criminal prosecution based on petitioners' failure to comply with them a violation of the Due Process Clause. The plain terms of the regulations foreclose that claim. The regulations provide that no ingredient is allowed unless it is "specified in this section." 21 C.F.R. 133.156(a). Calcium caseinate is not specified in the regulation defining mozzarella cheese, so it is not allowed. Compare 21 C.F.R. 135.110(a) (specifically allowing the addition of caseinate to ice cream and frozen custard); 21 C.F.R. 135.140 (specifically allowing the addition of caseinate to sherbert).

Petitioners argue (Pet. 7-8) that because skim milk may lawfully be used in making mozzarella

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[6] For that reason, petitioners err in relying (Pet. 20) on *Arizona* v. *California*, 460 U.S. 605, 618 & n.8 (1983), and *Liddell* v. *Missouri*, 731 F.2d 1294, 1304-1305 (8th Cir.), cert. denied, 469 U.S. 816 (1984).

cheese, see 21 C.F.R. 133.156(c)(1), calcium caseinate may also be used. They base this argument on the fact that it is permissible to add "other milk derived ingredients," of which caseinate is one, to skim milk. See 21 C.F.R. 131.143(c)(2). But even assuming that petitioners would have been allowed to use skim milk containing calcium caseinate, that is not what they did. They never used skim milk—with or without calcium caseinate—in their cheesemaking. Rather, petitioners added dry calcium caseinate directly to the raw milk as received from the producer. See Pet. 5. The "average person" (Pet. 23) who orders a glass of skim milk would not expect to receive dry calcium caseinate. Accordingly, even under petitioners' creative theory, they violated the FDA regulations and defrauded the government.[7]

In any event, petitioners' assertions regarding the vagueness of the regulations are belied by their own furtive actions. Their consistent course of conduct in seeking to conceal their use of calcium caseinate showed that they knew the FDA regulations and their contracts with the Commodity Credit Corporation prohibited the use of calcium caseinate. Peti-

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[7] The United States did not claim that the cheese petitioners delivered under the contracts was unhealthy or dangerous. Indeed, the cheese actually contained more protein than it should have. The "protein efficiency ratio" (Pet. 25) of the product, however, is beside the point. The contracts called for real cheese, and what petitioners supplied was imitation cheese.

Moreover, the assumption underlying petitioners' theory is incorrect. Title 21, Code of Federal Regulations, Section 131.143 defines a beverage "food" called skim milk, not an ingredient called skim milk to be used in other foods. See Pet. 24-25. This is clear from the regulation itself, which defines the "name of the food" and requires it to appear on the "label." 21 C.F.R. 131.143(e).

tioners try to explain away their coverup activities and their alteration of documents by the alleged need for secrecy in the cheese industry. That explanation is unconvincing, however, where, as here, government inspectors and auditors were the targets of petitioners' deception.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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